Quanta System Q1
LASER IN OUR DNA

Special 510(K) SUMMARY – Device Modifications **K141101**

Introduction:

This document contains the 510(k) Summary for the device Litho.
The basis of this submission is Modifications to Device already cleared.
The content of this summary is based on the requirements of 21 CFR 807.92(c).

Applicant / Manufacturer Name and Address:	Quanta System SPA Via IV Novembre, 116 Solbiate Olona (VA) Italy, 21058
510(k) Contact Person:	Maurizio Bianchi Regulatory Affairs Manager Quanta System SPA Email: maurizio.bianchi@quantasystem.com Phone: +39 0331 376797 Fax: +39 0331 367815

Date Prepared:	April 30th, 2014
Device Name:	Litho
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Basis for Submission:	Device modifications
Legally Marketed Device	Litho (K091909)

The modified device Litho is claimed to be derived from the legally marketed (unmodified) device Litho (K091909) because of Device modifications – update to the Third edition of IEC 60601-2-22 (basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment).

Performance Standards:

There are no mandatory performance standards for this device.

General Device Description:

The modified device Litho is a Laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).

This Special 510(k) of the modified device Litho is submitted due to Device Modifications of the already cleared device Litho (K091909) because of the sum of the incremental changes from the original clearance K091909. Is included the update to the third edition of IEC 60601-1 (*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) and to the collateral standards.

The modified device Litho has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1 µm.

The sum of the incremental changes from the original clearance K091009 has been taken into account and all the occurred modifications will be listed and described within this submission.

The device Litho including a fiber optic delivery system is intended to be used in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones.

The device Litho including a fiber optic delivery system is indicated for use in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones in medical specialties including, but not limited to: Urology, Gastroenterology, Arthroscopy, Neurosurgery, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

The modified device Litho is claimed to be derived from the legally marketed (unmodified) device Litho (K091909) because of the sum of the incremental changes from the original clearance K091909. Is included the update to the third edition of IEC 60601-1 (*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) and to the collateral standards.

Description of the modifications:

The modified device Litho is a Laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).
This Special 510(k) of the modified device Litho is submitted due to Device Modifications of the already cleared device Litho (K091909) because of the sum of the incremental changes from the original clearance K091909. Is included the update to the third edition of IEC 60601-1 (*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) and to the collateral standards.

The modified device Litho share the same architecture and the same laser source of the unmodified device Litho: both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1 µm, with no change in the fundamental scientific technology of the device.

The modified device Litho has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Under the new 510(k) Paradigm, referring to 21 CFR 807.81(a)(3) and the FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, the following modifications have been implemented on the cleared device Litho (K091909) without submitting a new 510(k):

- An alternative power-supply from a second source has been qualified.
- The water pump of the cooling system has been changed to improve the cooling efficiency.
- The water-to-air heat-exchanger has been changed to improve the cooling efficiency.
- The technical specifications of lens focusing the laser beam into the optical fiber has been changed to improve the incoupling.
- The footswitch connector has been moved to the front side of the device to improve the usability.
- A white LED ring around the fiber connector is lighting when the fiber is properly connected to the device (fiber interlock OK)
- An RFID recognition system has been added to read the fiber diameter directly from the fiber equipped with the suitable transponder.
- Review of the combinations of the laser parameters (energy and frequency) achievable within 30 W maximum power (upon physicians' feedbacks).
- The GUI (Graphic User Interface) has been changed to improve the readability (upon physicians' feedbacks).

During 2013 it has been performed the upgrade to the third edition of IEC 60601-1 and to its collateral standards for the European market (CE mark).
The upgrade to the third edition of the IEC 60601-1 and to its collateral standards leads to a basic change in the (regulatory) design input requirements with the subsequent revision of risk analysis and specific verification and validation activities to demonstrate that modified device meet the new requirements. All the modifications implemented until 2013 have been re-evaluated following the requirements of third edition of IEC 60601-1 and to its collateral standards.

Taking into account the FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, the upgrade to the third edition of the IEC 60601-1 and to its collateral standards has been evaluated as a relevant step of the evolution of the device and therefore it has been decided to submit this Special 510(k).

The overall dimensions and external appearance of the modified device are the same as the unmodified device (see picture 1-1)

Picture 1-1 – device Litho

Intended Use/Indications for Use

The modified device Litho is a Laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).
This Special 510(k) of the modified device Litho is submitted due to Device Modifications of the already cleared device Litho (K091909) because of the sum of the incremental changes from the original clearance K091909. Is included the update to the third edition of IEC 60601-1 (*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) and to the collateral standards.

The modified device Litho share the same architecture and the same laser source of the unmodified device Litho: both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1 µm, with no change in the fundamental scientific technology of the device.

The modified device Litho has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

The *Intended Use/Indication for use statement* of the unmodified device (Litho - K091009) has

been analized. In the original statement there is not a clear definition (separation) of the Intended use and of the Indications for use and thus a revised statement is proposed.
The revised version of the statement has separated sections for the *Inteded Use* and for the *Indications for use*.
Moreover, in order to have a more understandable definition of the *Indications for use*, it has been removed the (long) list of diseases/surgical operations given in K091909 because this list, as said by several physicians, does not add useful information.

Thus the Intended Use is:
The device Litho including a fiber optic delivery system is intended to be used in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones.

And the Indications for use are:
The device Litho including a fiber optic delivery system is indicated for use in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones in medical specialties including, but not limited to: Urology, Gastroenterology, Arthroscopy, Neurosurgery, Pulmonary, Gynecology, ENT, Dermatology , Plastic Surgery and General Surgery.

The modified device Litho has the same intended use of the unmodified device.

Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Substantial Equivalence:

This Special 510(k) of the modified device Litho is submitted due to Device Modifications of the already cleared device Litho (K091909) because of the sum of the incremental changes from the original clearance K091909. Is included the update to the third edition of IEC 60601-1 (*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) and to the collateral standards.

The modified device Litho share the same architecture and the same laser source of the unmodified device Litho: both devices are Pulsed Holmium:YAG laser with a maximum output power of 30 W @ 2.1 µm, with no change in the fundamental scientific technology of the device.

The modified device Litho has the same intended use of the unmodified device. Moreover the the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Thus the modified device Litho is substantially equivalent to the previously legally marketed device Litho (K091909).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 8, 2014

Quanta System SpA
Mr. Maurizio Bianchi
Regulatory Affair Manager
Via IV Novembre, 116
Solbiate Olona (VA) 21058, Italy

Re: K141101
Trade/Device Name: Litho
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 12, 2014
Received: June 16, 2014

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K141101

Device Name
Litho

Indications for Use (Describe)

INTENDED USE

The device Litho including a fiber optic delivery system is intended to be used in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones.

INDICATIONS FOR USE

The device Litho including a fiber optic delivery system is indicated for use in surgical procedures such as open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and in Lithotripsy of stones in medical specialties including, but not limited to:

- Urology
- Gastroenterology
- Arthroscopy
- Neurosurgery
- Pulmonary
- Gynecology
- ENT
- Dermatology
- Plastic Surgery
- General Surgery

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

David Krause -S

for BSA

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